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EXAMINER	
JOHNSON III, HENRY M	

ART UNIT	PAPER NUMBER
3769	

NOTIFICATION DATE	DELIVERY MODE
12/17/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/560,821	ARAI ET AL.	
	Examiner	Art Unit	
	HENRY M. JOHNSON III	3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18 and 22-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18 and 22-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 December 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *082608*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Response to Arguments

Applicant's arguments filed October 1, 2008 have been fully considered but they are not persuasive.

The irradiated light may only have one peak intensity. By definition peak is "the maximum value of a quantity during a specified time interval: a voltage peak". Thus the terms low peak and high peak in the disclosure are improper and confusing. The examiner interprets the intent is that a range of intensities exists that provide optimal PDT, that range having a low intensity value and a high intensity value.

The positively cited limitations of the apparatus claims are a light irradiating means and a control means, both of which are clearly anticipated by Parker et al. The functional language does not clearly indicate how the many variables required to properly control to a specific depth are determined or communicated to the controller, although such inputs would be obvious to a skilled artisan as indicated by Dougherty and Dumoulin-White et al. herein. Thus, the control means is interpreted as being capable of controlling as per the functional language. The microprocessor of Parker et al. meets that interpretation.

Specification

35 U.S.C. 112, first paragraph, requires the specification to be written in "full, clear, concise, and exact terms." The revision provided failed to yield a specification that meets the requirement. Many portions are unclear due to terms and phrases. One specific term is peak intensity that has multiple values; i.e. low peak intensity and high peak intensity as explained above. Another example is the term constant value on page 16, line 15 of the amended specification, where the term is not defined or explained. The examiner interprets that paragraph as intensity above the upper end of an effective range of intensities, may deform a superficial region. The specification must be clear such that multiple interpretations of the

invention do not result. The specification is replete with missing pronouns and tense errors that hinder clear understanding of the invention.

Claim Objections

Claims 13 and 29 cite achieving the peak intensity of the predetermined range. That would be, by definition, the highest intensity of the range. The examiner believes the intent was to achieve an intensity within the predetermined range. This highlights a concern with the term peak intensity throughout the disclosure.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The control means is enabled to control the operational parameters of the light. The depth in a body where the photosensitizer is activated is a result of the light intensity reaching the photosensitizer and the wavelength of the light. The activation is dependent on the characteristics of the photosensitizer. The irradiation intensity at a target depth is dependent on the attenuation of the light by the tissue and vessels. The control means is not enabled to process these variables.

Claim 17 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it

is most nearly connected, to make and/or use the invention. Means for measuring the cell death rate and providing same to a controller for calculation of control parameters is not disclosed. Without providing a cell death rate to the control means, no calculation based on that variable is possible.

Claim 17 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. A control means calculating an irradiation condition based on measurement of result of rate of cell death is new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 13, 17 and 29 recite the limitations “peak intensity”, "high peak intensity", and “peak intensity range”. The terms are not clearly defined in that a peak intensity, by definition, must have a single peak intensity. The term “high peak intensity” is unclear as high can be interpreted as a relative term.

Claim 1 recites the limitation "the wavelength" in line 5. There is insufficient antecedent basis for this limitation in the claim.

Claim 10 is unclear as the term “maintaining constantly the total number of pulse of the light” is not clear as to whether it refers to the pulse frequency or absolute number of pulses.

Claim 11 is indefinite as directed to intended use. The total energy is related to intensity over time and therefore is dependent on the time of treatment.

Claim 12 is unclear as a peak intensity has, by definition, a single value, yet the peak intensity is cited as changing.

Claim 13 recites the limitation "the photodynamic therapy" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 13 recites the limitation "the wavelength" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

Claims 13 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: determination of tissue type or attenuation properties of the tissue and a determination of the boundaries of the target and non-target areas. The depth limits of the superficial part would be required inputs for an intensity calculation.

Claim 17 is indefinite due to the term "and controls a rate of cell death damaged by...". It's the photosensitizer to kill or damage the cells?

Claim 18 is indefinite as the term "total number of a irradiation pulse" is not clear.

Claim 22 recites the limitation "the cell fatality rate" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 23 is indefinite as the term "total number of the irradiation pulse" is not clear.

Claim 23 recites the limitation "the cell fatality rate" in line 4. There is insufficient antecedent basis for this limitation in the claim.

Claim 24 is unclear as a peak intensity has, by definition, a single value, yet the peak intensity is cited as controlled or changing.

Claim 24 recites the limitation "the cell fatality rate" in line 4. There is insufficient antecedent basis for this limitation in the claim.

Claim 25 recites the limitation "the cell fatality rate" in line 4. There is insufficient antecedent basis for this limitation in the claim.

Claim 29 recites the limitation "the high peak intensity" in line 13. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4-6, 10-12, 17 and 22-25 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 4,592,361 to Parker et al. Parker et al. disclose an apparatus for delivering photodynamic therapy with a pulsed light source (Fig. 3, # 16) having a wavelength, intensity, pulse width and pulse rate controlled by a microprocessor (Col. 12, lines 3-14). Thus, the device is capable of controlling (control means) the intensity based on inputs to the microprocessor.

The language regarding the depth of photosensitizer and activation has no defined structure, but is related to the intended use of selectively activating the photosensitizer at a desired target.

Claim 1 only positively claims a controlled irradiation means. Parker et al. is capable of directing light of an intensity and pulse rate at a target area. How the light behaves in the tissue is dependent on the photosensitizer used, wavelength (a primary determinate of penetration depth), intensity and tissue properties. Altering the intensity (peak intensity) is clearly part of a control process. The microprocessor control of Parker et al. is capable altering the parameters as discussed above as required by the photosensitizer being used as is well known in the arts. Lacking specific structural limitations other than control means and irradiation means fails to provide finite metes and bounds and allows Parker et al. to be broadly interpreted to read on the claims.

Regarding claim 5, Parker et al. teach controlling the irradiation source using a detector to determine the level of oxygen available to avoid depletion that would inhibit singlet oxygen production (Col. 13, lines 25-35).

Regarding claim 6, Parker et al. disclose the light may be an Nd:YAG laser operating at a second harmonic (Col. 10, line 18). The controller of Parker et al. is capable of controlling the parameters of the laser

Regarding claim 29, Parker et al. discloses detecting fluorescence from a photosensitizing dye, thus it is inherent that such would have to be administered and irradiation is clearly done with the structure disclosed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 4,592,361 to Parker et al. as applied to claim 1 above and further in view of U.S. Patent Application Publication US 2003/0022105 to Prasad et al. Parker et al. are discussed above, but do not teach intensities or pulse rates. Prasad et al. discloses intensities for photodynamic therapy of from 0 to 200 MW/cm^2 (paragraph 0321) and pulse rates of from 0.1 Hz to 1 kHz (paragraph 0334). Control of light parameters in photodynamic therapy is pervasive in the art and, therefore, it would have been obvious to one skilled in the art to use the intensities and pulse rates as taught by Prasad et al. in the device of Parker et al. to obtain the light parameters required for a specific photosensitizer.

Claims 7-9 and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 4,592,361 to Parker et al. as applied to claims 1 and 17 above and further in view of U.S. Patent 5,514,669 to Selman. Parker et al. are discussed above, but do not teach the use of a catheter for delivery of light for photodynamic treatment. Selman teaches photodynamic therapy wherein the light energy is delivered to a patient's prostate by placing the light delivery means in a urethral catheter. The light delivery means is properly located within the urethra and positioned adjacent to the target prostate tissue. A balloon may be affixed to the distal end of the catheter (Col. 5, lines 15-25). It would have been obvious to one skilled in the art to use the

catheter as taught by Selman in the device of Parker et al. as the use of such catheters is pervasive in the arts.

Claims 13-16 and 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 4,592,361 to Parker et al. in view of U.S. Patent 6,413,267 to Dumoulin-White et al. and U.S. Patent 5,145,863 to Dougherty. Parker et al. are discussed above, but do not teach methodology for achieving an intensity at a specific depth in tissue. Dougherty teaches a method for destroying cells using photoradiation of target tissue with a photosensitizer, wherein a specific depth is known and the intensity determined for specific depths. With the attenuation constant known, the depth of penetration of a minimum irradiance or conversely the required irradiance for a minimum intensity at a given distance may be calculated. (Col. 18, lines 49-54). Dumoulin-White et al. disclose a method to estimate the depth dependence of intensity (i.e., the attenuation of intensity as a function of depth) in tissue being treated. For example, the radial dependence can be used to generate a curve or formula for a curve, which can in turn be used to select a depth dependence curve or formula from a look-up table. In any event, the intensity (or irradiance) of radiation at target depth is determined from the depth dependence curve or formula, and the radiant exposure at target depth is determined by, e.g., integration (Col. 5, lines 40-49). An inherent feature of all photosensitizers is a range of activation. It would have been obvious to one skilled in the art to use the techniques for determining an intensity at specific depths in tissue as taught by Dougherty and Dumoulin-White et al. to control the radiation of Parker et al. to control a photodynamic process. A skilled artisan would know the activation characteristics of the photosensitizer used and the depths to be treated and would be motivated to insure the proper intensity required was delivery at the proper location or locations.

Regarding claim 30, the various methods for delivery of a photosensitizer and well known in the art (see Selman cited above).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication should be directed to HENRY M. JOHNSON III at telephone number (571)272-4768.

/Henry M. Johnson, III/
Supervisory Patent Examiner, Art Unit 3769

12/12/2008